

REQUEST FOR RECONSIDERATION

Claims 1 to 6, 8 to 16, 28 to 33, 41 and 42 as set forth in the attached Appendix I are now pending in this case. Claims 41 and 42 have been added as indicated.

New Claims 41 and 42 further specify the pH which is set in order to flocculate the proteinaceous protecting colloid together with the active compound out of the dispersion as required in subsection (b) of Claims 1 and 28. The specified pH range is addressed on page 17, indicated lines 18 to 20, of the application, and new Claims 41 and 42, therefore, don't add new matter.

Claims 1 to 6, 8 to 16 and 28 to 33 stand rejected under the provisions of 35 U.S.C. §102(b) and 103(a) as being unpatentable in light of the teaching of *Horn et al.* (US 4,522,743).

It is respectfully submitted that anticipation under Section 102 can be found only if a reference shows exactly what is claimed¹⁾. That means that the identical subject matter has to be shown in the reference in as complete detail as is contained in the claim²⁾. In other words, the test for anticipation is one of identity, the identical invention must be shown in the reference in as complete detail as is contained in the claim³⁾. In fact, the Federal Circuit has stated that it is error to treat claims as a catalog of separate parts, in disregard of the part-to-part relationships set forth in the claims that give those claims their meaning⁴⁾.

One of the essential requirements which characterize applicants' invention as defined in the claims at issue is that the proteinaceous protecting colloid and the active compound are flocculated out together⁵⁾. The teaching of *Horn et al.* fails to identically describe such a step. *Horn et al.* teach a preparation of carotenoid composi-

1) Cf. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (CAFC 1985); *In re Marshall* 577 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Kalm* 378 F.2d 959, 154 USPQ 10 (CCPA 1967).

2) Cf. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (CAFC 1989); *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (CAFC 1984).

3) Cf. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (CAFC 1989).

4) Cf. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (CAFC 1984).

5) Cf., for example, stage (b) in applicants' Claims 1 and 28.

tions wherein⁶⁾:

- 1) the carotenoid is dissolved in a volatile, water miscible, organic solvent at from 50 to 200°C to obtain a carotenoid solution;
- 2) the carotenoid solution which is obtained in step (1) is rapidly mixed with an aqueous solution of a swellable colloid at from 0 to 50°C to obtain a dispersion which contains a carotenoid precipitate in an extremely finely divided form⁷⁾;
- 3) the dispersion containing the precipitated carotenoids in extremely finely divided form is freed from the solvent and the dispersion medium.

Additionally, *Horn et al.* describe measures which can be taken to increase the concentration of the finely divided carotenoids in the dispersion formed in step (2)⁸⁾. These measures aim at maintaining the finely divided carotenoids in the liquid phase⁹⁾ while, at the same time, separating excess amounts of the swellable colloid from the liquid phase. The separation of the excess amounts of the swellable colloid is achieved according to the teaching of *Horn et al.* "either by addition of salt or by bringing ... [the dispersion] to a suitable pH"¹⁰⁾. Since the process addressed in the teaching of *Horn et al.* specifically aims at maintaining the finely divided carotenoids in the liquid phase¹¹⁾ it is clear that the conditions under which the salt is added or the "suitable pH" which is adjusted are such that the sedimentable coacervate which is formed does not comprise the finely divided carotenoids. The process of *Horn et al.*, therefore, does not comprise a step in which a proteinaceous protecting colloid and an active compound are flocculated out together. In light of the foregoing, the teaching of *Horn et al.* cannot be considered as an identical description of applicants' invention, particularly with regard to the part-to-part relationship of measures taken and results achieved by those measures which is set forth in applicants' claims and which give applicants' claims their meaning. It is therefore respectfully requested that the rejection of Claims 1 to 6, 8 to 16 and

6) Cf. col. 2, indicated lines 36 to 51, of *US 4,522,743*.

7) Cf. col. 3, indicated lines 60 to 64, of *US 4,522,743*.

8) Cf. col. 3, indicated line 65, to col. 4, indicated line 10, of *US 4,522,743*.

9) Cf., in particular, col. 4, indicated lines 4 and 5, of *US 4,522,743*.

10) Cf., in particular, col. 4, indicated line 68, to col. 5, indicated line 4, of *US 4,522,743*.

11) Cf. ftn. (9).

28 to 33 under Section 102(b) based on the teaching of *Horn et al.* be withdrawn. Favorable action is respectfully solicited.

For essentially the same reasons, the teaching of *Horn et al.* cannot be considered to render the subject matter of applicants' claims *prima facie* obvious within the meaning of Section 103(a). As explained in MPEP §2143, one of the three basic criteria which have to be met in order to establish a *prima facie* case of obviousness is that there must be some suggestion which would motivate a person of ordinary skill in the art to modify the reference as needed to arrive at the claimed subject matter. The suggestion to make the claimed combination must be found in the prior art and cannot be based on the applicant's disclosure¹²⁾.

The teaching of *Horn et al.* cannot be considered to provide the motivation or suggestion which is necessary for a finding of obviousness under Section 103(a) because flocculating out the swellable colloid and the finely divided carotenoids together reduces the concentration of the active ingredient in the liquid phase which is the opposite of the increase in concentration which is sought according to the teaching of *Horn et al.* Also, flocculating out the swellable colloid and the finely divided carotenoids together as required in accordance with applicants' invention changes the principle underlying the process of *Horn et al.* Where the proposed modification of the prior art would change the principle of operation of the prior art invention which is being modified, the teaching of the prior art is not sufficient to render a claimed invention *prima facie* obvious¹³⁾. The teaching of *Horn et al.* can, in light of the foregoing, not be considered to render applicants' invention obvious within the meaning of Section 103(a). Favorable reconsideration of the Examiner's position and withdrawal of the respective rejection is therefore respectfully solicited.

The foregoing equally applies to the subject matter of applicants' Claims 41 and 42 which depend upon Claims 1 and 28, respectively¹⁴⁾. In addition to the features which are incorporated by reference to Claim 1 or 28, new Claims 41 and 42 require that the proteinaceous protecting colloid be flocculated together with the active

12) Cf. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, 1442 (CAFC 1991).

13) Cf. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

14) If an independent claim is non-obvious under 35 U.S.C. §103, then any claim depending therefrom is non-obvious (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (CAFC 1988)).

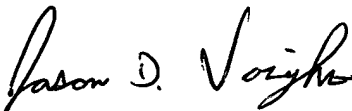
compound out of the dispersion by setting the pH to a value within one pH unit above the isoelectric point of the protein and one pH unit below the isoelectric point of the protein. This additional requirement which is specified in Claims 41 and 42 is also neither taught nor suggested by the teaching of *Horn et al.* The subject matter defined in the new claims is therefore even further removed from the teaching of *Horn et al.* than the subject matter of the claims upon which the new claims depend. Favorable action is respectfully solicited.

REQUEST FOR EXTENSION OF TIME:

It is respectfully requested that a three month extension of time be granted in this case. The respective \$1,020.00 fee is paid by credit card (Form PTO-2038 enclosed).

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account No. 14.1437. Please credit any excess fees to such deposit account.

Respectfully submitted,
NOVAK DRUCE DELUCA & QUIGG


Jason D. Voight
Reg. No. 42,205

1350 Connecticut Ave, N.W.
Washington, D.C. 20036
(202) 659-0100

Encl.: THE LISTING OF CLAIMS (Appendix I)

JDV/BAS

A P P E N D I X I:

THE LISTING OF CLAIMS:

1. (previously presented) A process for producing solid preparations of at least one water-soluble, sparingly water-soluble or water-insoluble active compound suitable for the food and animal feed sectors or for pharmaceutical and cosmetic applications by
 - a) dissolving or dispersing at least one of the abovementioned active compounds in an aqueous molecular dispersion or colloidal dispersion of a proteinaceous protecting colloid,
 - b) flocculating the proteinaceous protecting colloid together with the active compound out of the dispersion by setting the pH of the dispersion to a value which is in the range of the isoelectric point of the protein used as protecting colloid, and
 - c) separating off the flocculated solid from the water and any solvents additionally used and subsequently converting them into a dry powder.
2. (original) A process as claimed in claim 1 for producing solid preparations of at least one sparingly water-soluble or water-insoluble active compound suitable for the food and animal feed sectors or for pharmaceutical and cosmetic applications, wherein, in process step a), at least one of the abovementioned active compounds is dispersed in an aqueous molecular dispersion or colloidal dispersion of a proteinaceous protecting colloid.
3. (original) A process as claimed in claim 2, wherein the dispersion step a) is the production of a suspension of at least one solid active compound in an aqueous molecular dispersion or colloidal dispersion of a proteinaceous protecting colloid.
4. (original) A process as claimed in claim 3, wherein the suspension produced in process step a) is ground before the flocculation.
5. (original) A process as claimed in claim 2, wherein the dispersion in stage a) comprises the following steps:
 - a₁) dissolving one or more sparingly water-soluble or water-insoluble active compounds in a water-miscible organic solvent or a mixture of water and a water-miscible organic solvent or

- a₂) dissolving one or more sparingly water-soluble or water-insoluble active compounds in a water-immiscible organic solvent and
 - a₃) mixing the solution obtained by a₁) or a₂) with an aqueous molecular dispersion or colloidal dispersion of a proteinaceous protecting colloid, the hydrophobic phase of the active compound being produced as nanodisperse phase.
6. (original) A process as claimed in claim 5, wherein, when process step a₂) is being performed, the water-immiscible solvent is distilled off before flocculating the protecting colloid.
7. (canceled)
8. (original) A process as claimed in claim 1, wherein the protecting colloid is casein or a caseinate.
9. (original) A process as claimed in claim 1, which involves the production of carotenoid-containing dry powders.
10. (original) A process as claimed in claim 9 for producing dry powders comprising carotenoids selected from the group consisting of astaxanthin, β -carotene, β -apo-8'-carotenal, β -apo-8'-carotenic acid ethyl ester, canthaxanthin, citranaxanthin, echinenone, lutein, lycopene and zeaxanthin.
11. (original) A process as claimed in claim 9, wherein
- a) one or more carotenoids are dissolved in a water-miscible organic solvent, or a mixture of water and a water-miscible organic solvent, at temperatures above 30°C,
 - b) the resultant solution is mixed with an aqueous casein solution or caseinate solution,
 - c) the casein or caseinate is flocculated out of the dispersion together with the carotenoid at a pH of the dispersion which is in the region of the isoelectric point of casein or caseinate,
 - d) the flocculated solid is separated off from the water and solvent and dried.
12. (original) A solid preparation of at least one water-soluble, sparingly water-soluble or water-insoluble active compound suitable for the food and animal feed sectors or for pharmaceutical

and cosmetic applications and obtainable by a process as defined in claim 1.

13. (original) A solid preparation as claimed in claim 12 comprising at least one sparingly water-soluble or water-insoluble active compound suitable for the food and animal feed sectors or for pharmaceutical and cosmetic applications.
14. (original) A solid preparation as claimed in claim 12 having an active compound content of from 0.1 to 80% by weight.
15. (original) A solid preparation as claimed in claim 13 which is a carotenoid-containing dry powder.
16. (original) A dry powder as claimed in claim 15 comprising carotenoids selected from the group consisting of astaxanthin, β -carotene, β -apo-8'-carotenal, β -apo-8'-carotenic acid ethyl ester, canthaxanthin, citranaxanthin, echinenone, lutein, lycopene and zeaxanthin.
17. (canceled)
18. (canceled)
19. (canceled)
20. (canceled)
21. (canceled)
22. (canceled)
23. (canceled)
24. (canceled)
25. (canceled)
26. (canceled)
27. (canceled)
28. (previously presented) An oily suspension comprising, as disperse phase, solid preparations of at least one water-soluble, sparingly water-soluble or water-insoluble active compound suitable for the food and animal feed sectors or for pharmaceutical and cosmetic applications which are obtainable by

- a) dissolving or dispersing at least one of the abovementioned active compounds in an aqueous molecular dispersion or colloidal dispersion of a proteinaceous protecting colloid,
 - b) flocculating the proteinaceous protecting colloid together with the active compound out of the dispersion by setting the pH of the dispersion to a value which is in the range of the isoelectric point of the protein used as protecting colloid,
- and
- c) separating off the flocculated solid from the water and any solvents additionally used and subsequently converting them into a dry powder.
29. (original) An oily suspension as claimed in claim 28 having an active compound content of from 0.1 to 50% by weight, based on the total amount of oily suspension.
30. (original) An oily suspension as claimed in claim 28 comprising as active compound at least one carotenoid selected from the group consisting of astaxanthin, β -carotene, β -apo-8'-carotenal, β -apo-8'-carotenic acid ethyl ester, canthaxanthin, citranaxanthin, echinenone, lutein, lycopene and zeaxanthin.
31. (previously presented) A process for producing a carotenoid-containing oily suspension comprising, as disperse phase, at least one carotenoid selected from the group consisting of astaxanthin, β -carotene, β -apo-8'-carotenal, β -apo-8'-carotenic acid ethyl ester, canthaxanthin, citranaxanthin, echinenone, lutein, lycopene and zeaxanthin, which carotenoid is enclosed by one or more protecting colloids, with the proviso that the oily suspension comprises no water-soluble vitamins, which process comprises
- a) grinding a dry powder comprising the at least one carotenoid enclosed by one or more protecting colloids in at least one oil to a mean particle size of from 0.1 to 100 μ m or
 - b) grinding a dry powder comprising the at least one carotenoid enclosed by one or more protecting colloids without using a continuous phase to a mean particle size of from 0.1 to 100 μ m and then suspending the ground particles in at least one oil or
 - c) grinding a carotenoid-containing suspension comprising, as solid phase, the at least one carotenoid enclosed by one or more protecting colloids and, as dispersion medium, water or

a mixture of water and a water-miscible solvent to a mean particle size of from 0.1 to 100 μm , then freeing the solid phase from the water or water/solvent mixture and suspending the resultant ground particles in at least one oil.

32. (*original*) A process as claimed in claim 31, wherein the oil is an edible oil liquid at 20°C.
33. (*original*) A process as claimed in claim 31, wherein the oil is a hard fat solid at 20°C.
34. (*canceled*)
35. (*canceled*)
36. (*canceled*)
37. (*canceled*)
38. (*canceled*)
39. (*canceled*)
40. (*canceled*)
41. (*new*) The process of claim 1, wherein the proteinaceous protecting colloid and the active compound are flocculated by setting the pH value in stage (b) in a range of from one pH unit above the isoelectric point of the protein to one pH unit below the isoelectric point of the protein.
42. (*new*) The suspension defined in claim 28, which is obtained by a process in which the proteinaceous protecting colloid and the active compound are flocculated by setting the pH value in stage (b) in a range of from one pH unit above the isoelectric point of the protein to one pH unit below the isoelectric point of the protein.